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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/761,143 01/16/01 NAIR

M MSU 4.1-5441

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HM22/0328

EXAMINER

PATTEN, P

ART UNIT	PAPER NUMBER
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1651

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DATE MAILED:

03/28/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No. <b>09/761,143</b>	Applicant(s) <b>Nair et al.</b>
Examiner <b>Patricia Patten</b>	Group Art Unit <b>1651</b>

Responsive to communication(s) filed on \_\_\_\_\_.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

Claim(s) 1, 3-6, 15-18, and 27-30 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1, 3-6, 15-18, and 27-30 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 3 and 4

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1651

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

Claims 1, 15, 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a method for inhibiting cyclooxygenase or prostaglandin H synthase comprising providing cyanidin with at least one of the enzymes so that the cyanidin inhibits the enzymes. This statement lacks antecedent basis in the Specification because the Specification teaches administration of cyanidin (or flavanols) alone, but not in combination with the enzyme. The claim is interpreted to mean that the administered composition comprises a cyanidin and an enzyme. Because the claims are read in light of the specification, it is deemed that the intention of Applicants were to claim a method for inhibiting COX enzymes or prostaglandin synthase enzymes via administration of cyanidin alone (or admixed with carriers). Claims were examined on the merits as such, however, correction is in order to avoid confusion.

Claim 15 recites the term 'the compound.' This term lacks antecedent basis in claim 1. Correction is necessary.

Claim 17 recites 'the ratio of...'. This term lacks antecedent basis in claim 15.

Art Unit: 1651

Claim 18 recites 'the compound.' There is lack of antecedent basis for this phrase in claim 1.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Lietti et al. (GB 1,589,294). Claims 27 is drawn to a method for inhibiting cyclooxygenase or prostaglandin H synthase comprising administration of a cyanidin. Claims 28 and 29 are drawn to the method of Claim 27 wherein the compound is from a tart or sweet cherry.

Lietti et al. (GB 1,589,294) disclosed that anthocyanidins, and specifically cyanidin possessed anti-inflammatory activities (pp.1, lines 11-33 and especially 'cyanidine' structure).

Because Lietti et al. proposed cyanidin, and because the structure of cyanidin is constant, independent upon the source, one of ordinary skill in the art would have reasonably ascertained that cyanidin from any source would have acted equivalently because they are exactly the same phytochemical. It was known at the time of the instant application, as admitted by Applicants (pp. 2, Instant Specification), that cherries were a source of cyanidin. Thus, the source of cyanidin does not materially change the method.

Art Unit: 1651

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 30 is rejected under 35 U.S.C. 103(a) as obvious over Lietti et al. (GB 1,589,294).

Claim 30 is drawn to where the cyanidin is administered to a human.

The teachings of Lietti et al. were discussed *supra*. Lietti et al. did not specifically mention where the cyanidin was administered to humans.

One of ordinary skill in the art would have reasonably ascertained that the phytochemicals proposed by Lietti et al. which were useful for treating conditions such as inflammation would have beneficially effected a human. One would have had a reasonable expectation of success because Lietti et al. clearly demonstrated that the anthocyanidins were useful in animals (Claim 16 for example), and consequently because animals were an acceptable model for human inflammation at the time the invention was made.

Art Unit: 1651

Claims 1, 3-4, 5-6 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wurm et al. (1982). Claims 1, 3-4, 5-6 and 15-18 are drawn to a method for inhibiting cyclooxygenase or prostaglandin H synthase via administration of a cyanidin. Claims are further drawn to where the cyanidin is obtained from sweet or tart cherries, wherein the method is performed in-vivo or in-vitro, wherein the cyanidin is incorporated into a dried mixture of isolated anthocyanins, bioflavanoids and phenolics along with a food grade carrier, wherein the carrier is a dried cherry pulp, wherein the ratio of dried mixture to carrier is between about 0.1 to 100 and 100 to 0.1 and wherein the cyanidin is incorporated into a food.

Wurm et al. (1982-English Translation) specifically taught that “All flavonoids, regardless of the stereochemistry and degree of oxidation of their heterocyclic rings, are prostaglandin synthetase (PGS) inhibitors if at least one ring has a pyrocatechol structure” (pp. 6, English Translation). Cyanidin fits Wurm et al.’s flavonoid description, as evidenced by the structure of cyanidin given by Lietti et al. (Please see structure on pp. 1).

Cyanidin has a pyrocatechol structure, and thus, one of ordinary skill in the art would have had a reasonable expectation that cyanidin, although not specifically mentioned by Wurm et al., would have inhibited prostaglandin synthase.

Claims which are specific as to the origin of the cyanidin do not materially change the method claim. It would have been obvious, in light of the teachings of Wurm et al. to have used cyanidin from any source because it was known that flavonoids with pyrocatechol structures were

Art Unit: 1651

PGS inhibitors. Moreover, it was readily known that cyanidin was obtainable from cherries as readily admitted by Applicants.

It would have been further obvious to have incorporated cyanidin, a known PGS inhibitor into a formulation comprising carriers or mixtures of different flavanoids such as anthocyanins in different ratios, because, again, it was already known that flavonoids, with structures such as cyanidin inhibited PGS. Furthermore, claims to where the active ingredient is further included in a carrier and/or food does not materially change the method for inhibiting prostaglandin synthase or cyclooxygenase. The method is deemed to be the same method because the active ingredient in the present case is cyanidin. Hence, it would have been obvious to have administered cyanidin in any form, with a carrier, or with food because it was already known that phytochemicals with pyrocatechol structures inhibited PGS alone. Thus, the addition of food and/or carriers would have required nothing more than routine randomization of result effective variables.

Varying individual levels of constituents in a pharmaceutical preparation was considered routine experimental procedure at the time of the instant invention. One of ordinary skill in the art would have been motivated to have modified the proportions of active ingredients in the composition in order to enable the content of the preparation to be matched with the demands and needs of individuals which needed treatment.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at

Art Unit: 1651

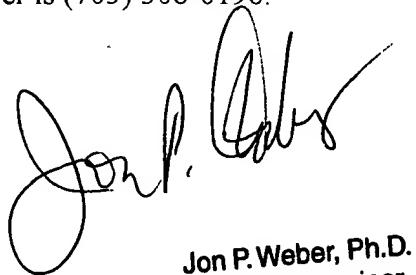
the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Jon P. Weber, Ph.D.  
Primary Examiner